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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,885	03/29/2006	Craig L. Nessler	01640421AA	8840
30743 7590 09/02/2008 WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C. 11491 SUNSET HILLS ROAD SUITE 340 RESTON, VA 20190				
EXAMINER KUBELIK, ANNE R				
ART UNIT		PAPER NUMBER		
1638				
MAIL DATE		DELIVERY MODE		
09/02/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/538,885

**Applicant(s)**

NESSLER ET AL.

**Examiner**

Anne R. Kubelik

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

DETAILED ACTION

1. Claims 13-19 are pending.
2. The restriction among the different enzymes in Group II is withdrawn, as art on all groups was found. Claims 13-19 are examined.
3. 35 USC 112, 6<sup>th</sup> paragraph, has been invoked for claim 15.
4. The objection to claims 14 and 15 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of Applicant's amendment of the claims.
5. The rejection of claims 13-15 and 20 under 35 U.S.C. 102(b) as being anticipated by Jain et al (2000, Molecular Biology 6:73-78) is withdrawn in favor of the new rejections below.
6. The rejection of claims 13-16, 19-20 under 35 U.S.C. 103(a) as obvious over Jain et al (2000, Molecular Biology 6:73-78) in view of Arner et al (2001, Biochem J. 360:313-320) is withdrawn in favor of the new rejections below.
7. The rejection of claims 13-16, 19-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the teachings in the art.
8. The rejection of claims 13-16, 19-20 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing endogenous Vitamin C by transforming plants with At-MIOX4, does not reasonably provide enablement for reducing TSNAs in tobacco with at least one gene in a Vitamin C biosynthetic pathway is withdrawn in light of the teachings in the art.

*Claim Rejections - 35 USC § 112*

9. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no disclosure in the specification to describe the means for enhancing transcription of said gene or genes. There is no description of the structure or materials perform the function in the “means for” limitation.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 13 is indefinite in its recitation of “TSNAs”. Abbreviations should be defined in the claim.

Claim 15 is indefinite in its recitation of “means for enhancing transcription of said gene or genes” as no associate structure is defined.

***Claim Rejections - 35 USC § 103***

12. Claims 13-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al (US 2004/0185562, filed March 2001) in view of Rundlöf et al (2000, J. Agric. Food. Chem. 48:4381-4388).

The claims are drawn to a method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway and has increased endogenous levels of vitamin C, wherein the gene encodes myo-inositol oxygenase.

Schroeder et al teach a method of producing ascorbic acid in plants by expressing in them a gene encoding myo-inositol oxygenase (claim 90). Schroeder et al teach that these plants include tobacco (¶130). Because the plants express the protein, they have a means for enhancing transcription of said gene. Schroeder et al do not teach air curing the tobacco.

Rundlöf et al teach that ascorbic acid inhibits TSNA formation in air-cured tobacco plants (paragraph spanning the columns on pg 4387; Table 4).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to air cure the tobacco plants Schroeder et al as described in Rundlöf et al. One of ordinary skill in the art would have been motivated to do so because Rundlöf et al teaches that ascorbic acid inhibits formation of TSNA's, which are undesirable, in air-cured tobacco plants. It would have been obvious to one of ordinary skill in the art to express more than one copy of the gene in the plants; one of ordinary skill in the art would have been motivated to do so to obtain higher levels of ascorbic acid in the plants. The pathway in which myo-inositol oxygenase works contains an L-gulonono- $\gamma$ -lactone oxidase enzyme.

13. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (2000, Molecular Breeding 6:73-78) in view of Rundlöf et al (2000, J. Agric. Food. Chem. 48:4381-4388).

The claims are drawn to a method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway and has increased endogenous levels of vitamin C, wherein the gene encodes L-gulono- $\gamma$ -lactone oxidase.

Jain et al teach tobacco plants transformed with a gene encoding rat L-gulono- $\gamma$ -lactone oxidase; the plants have 7 times more ascorbic acid than non-transformed plants (pg 76, left column, paragraphs 1-2). The 35S promoter is the means for enhancing transcription of said gene (pg 76, left column, paragraph 1). Jain et al do not teach air curing the tobacco plants.

Rundlöf et al teach that ascorbic acid inhibits TSNA formation in air-cured tobacco plants (paragraph spanning the columns on pg 4387; Table 4).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to air cure the tobacco plants taught by Jain et al as described in Rundlöf et al. One of ordinary skill in the art would have been motivated to do so because Rundlöf et al teaches that ascorbic acid inhibits formation of TSNAs, which are undesirable, in air-cured tobacco plants. It would have been obvious to one of ordinary skill in the art to express more than one copy of the gene in the plants; one of ordinary skill in the art would have been motivated to do so to obtain higher levels of ascorbic acid in the plants. The pathway in which L-gulono- $\gamma$ -lactone oxidase works contains a myo-inositol oxygenase enzyme.

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al in view of Rundlöf et al as applied to claims 13-18 above, and further in view of Arner et al (2001, Biochem J. 360:313-320).

The claims are drawn to a method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway and has increased endogenous levels of vitamin C, wherein the gene encodes myo-inositol oxygenase.

The teachings of Jain et al in view of Rundlöf et al are discussed above. Jain et al in view of Rundlöf et al do not teach a gene encoding myo-inositol oxygenase.

Arner et al teach a gene encoding myo-inositol oxygenase (Fig 3) and that myo-inositol oxygenase converts myo-inositol to D-glucuronate (Fig 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method comprising air-curing a genetically engineered plant that is transformed with a gene in a vitamin C pathway taught by Jain et al in view of Rundlöf et al to use the gene encoding myo-inositol oxygenase described in Arner et al as the gene in the pathway. One of ordinary skill in the art would have been motivated to do so because Arner et al teach that myo-inositol oxygenase converts myo-inositol to D-glucuronate (Fig 1), which Jain et al teach is one of the intermediates in the animal vitamin C biosynthetic pathway (Fig 1). Substitution of one enzyme in the pathway for another is an obvious design choice and an optimization of design parameters. Further, Jain et al suggests using one or more enzymes in the animal pathway (pg 73, right column, paragraph 2),

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*Conclusion*

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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September 2, 2008

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638